DEC 1 3 2001

K013815

MEDRAD®

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name:	Medrad Inc.
Submitter's Address:	One Medrad Drive, Indianola, PA 15051 USA
Telephone Number:	(412) 767-2400, ext. 3536
Fax Number:	(412) 767-2499
Contact Person:	Frank Pelc
Date:	November 15, 2001
Proprietary Name:	Quik-Fit Syringe
Common Name:	Syringe, Angiographic
Classification:	Class II, DXT
Classification Name:	Injector and Syringe, Angiographic
Predicate Device:	Medrad Disposable Syringes: K964642

Device Description - The Medrad Quik-Fit Syringe comprises a clear plastic syringe barrel with a plunger assembly that moves within the inside of the barrel to deliver fluid. The syringe fits onto Medrad powered injectors, and holds contrast media and flushing solutions for delivery by the injector into humans.

Description of Changes - This Special 510(k) premarket notification is being submitted due to modifications to the syringe plunger assembly.

Substantial Equivalence - The modified Medrad Quik-Fit Syringe described in this 510(k) premarket notification is substantially equivalent to the Medrad Quik-Fit Syringes described in K964642. The performance specifications, intended use, labeling, packaging, and sterilization process for the proposed, modified device are unchanged from the current, predicate device. Biocompatability and functional testing relative to the modifications have been satisfactorily completed to show that it is as safe and effective as the current device.

A table comparing the features of the predicate device and modified device is provided below.

Comparison of Features

Feature	Predicate Device (K964642)	Proposed Device
Packaging	Same	Same
Labeling	Same	Same
Shelf Life	5 Years	Same
Single Use	Yes	Yes
Intended Use	Medrad Qwik-Fit Syringes are intended to assist in the intravascular delivery of contrast media and flushing solutions at controlled flow rates and volumes.	Same
Indications for Use	Medrad Qwik-Fit Syringes are indicated to contain and hold contrast media and assist in delivery of same, to effect CT and MRI diagnostics. They are indicated for single-use only.	Same
Sterility	Ethylene Oxide (EtO) at 8.4% and 91.6% HCFC-124	Same
Plunger Materials In Contact With Fluid Path	Synthetic Polyisoprene	Thermoplastic Elastomer and ABS polymer
Latex Content	Latex Free	Same
Parameters for Use	All available Injector/Syringe configurations & volume options	Same
Pressure Capabilities Compatable With Intended Injectors	Yes	Yes

Quality for Life

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Frank W. Pelc III
Regulatory Affairs Coordinator
Medrad, Inc.
One Medrad Drive
Indianola, PA 15051-0780

DEC 1 3 2001

Re: K013815
Medrad Qwik-Fit Syringe
Regulation Number: 870.1650
Regulation Name: Angiographic injector and syringe.
Regulatory Class: Class II
Product Code: DXT
Dated: November 15, 2001
Received: November 16, 2001

Dear Mr. Pelc:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K013815

Device Name: Medrad Qwik-Fit Syringe

Indications for Use/Intended Use:

Medrad Qwik-Fit Syringes are indicated to contain and hold contrast media and assist in delivery of same, to effect CT and MRI diagnostics. They are indicated for single-use only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013815

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)